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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,885

11/10/2006

Marshall David Crew

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152 7590 10/13/2011
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EXAMINER

SOROUGH, ALI

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

10/13/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/596,885	Applicant(s) CREW ET AL.	
	Examiner ALI SOROUGH	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 20 and 22-34 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 20 and 22-34 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/22/2011 has been entered.

Claim Status

Claims 20 and 22-34 are pending.

Claims 1-19 and 21 are previously cancelled.

Claims 20 and 22-34 have been examined.

Claims 20 and 22-34 are rejected.

Priority

Priority to PCT/IB04/04260 filed on 12/20/2004 which claims priority to application 60/533848 filed on 12/31/2003 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following rejection is reiterated from the previous Office Action.

1. Claims 20-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Infeld et al. (International Application Published Under the PCT WO 02/089835 A2, Published 11/14/2002) in view of Babcock et al. (European Patent Application 1027886 A2, Published 08/16/2000).

The claims are directed to solid composition comprising particles of at least 10% low-solubility amorphous drug, 30 to 65% poloxamer, and a at least 5% stabilizing polymer such as hydroxypropyl methyl cellulose acetate succinate (HPMCAS). The claims are further directed to an anti-viral drug. The claims are further directed to the amount of HPMACS being present such that the MDC of the drug is increased at least 1.25 fold over a control.

Infeld et al. show a tablet comprising a kernel having 61.3% nelfinavir mesylate (chemical name: N-(1,1-dimethylethyl)decahydro-2-[2-hydroxy-3-[(3-hydroxy-2-methylbenzoyl)amino]-4-(phenylthio)butyl]-3-isoquinoline carboxamide monomethanesulphonate), 33.1% poloxamer 188, 3.4% microcrystalline cellulose, corn starch, and magnesium stearate. (page 12, example 5). Nelfinavir mesylate is an low-soluble, amorphous, hydrophobic antiviral drug. (page 1, Lines 5-28). The drug kernel is made by melt granulation process which results in the formation of particles. (page 6, Lines 7-15). The presence of poloxamer enhances the bioavailability of the drug. (page 2, Lines 15-16).

Infeld et al. lacks a teaching wherein the particles further comprise a stabilizing polymer such as hydroxypropyl methyl cellulose acetate succinate (HPMCAS).

Babcock et al. show a solid dispersion of a low-solubility drug and a polymer. (abstract). The preferred polymer is cellulosic. (page 29, Lines 19-36). The most preferred polymer is the stabilizing polymer HPMCAS. (page 33, Lines 23-27, prior art claim 57). HPMC will stabilize amorphous low-soluble drugs so that they do not undergo change to crystalline form overtime during storage. (page 3, Lines 5-14). This dispersion

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provides an MCD and AUC of 1.25 fold over a control composition. (page 7, Lines 17-30). In preferred embodiment 30% HPMACS is present in an example dispersion (page 18, lines 20-25).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the composition of Infeld et al. by adding HPMCAS taught by Babcock et al. to the composition. One of ordinary skill in the art would have been motivated to do so in order to provide enhanced stability to the tablet formulation of Infeld et al. With regard to the instantly claimed glass transition temperature of the particle and drug as instantly claimed, it would be expected that the particles taught by Infeld et al. as modified by Babcock et al. would also possess this property. With regard to the instantly claimed method of making the composition, this is a product-by-process limitation that is not given patentable weight in a product claim.

Response to Applicant's Arguments

Applicant argues that that HPMCAS does not meet the definition of the stabilizing polymer of Babcock et al. because it teaches that it does not meet the limitation that the polymer has a glass transition temperature of at least 100°C at 50% relative humidity.

Applicant's argument has been fully considered but found not to be persuasive.

Paragraphs 57-58 of Babcock et al. do not indicate that HPMCAS is excluded. Stoyer et al. teach that HPMCAS has a glass transition of 135°C (p. 1344, Table 1). Therefore, HPMCAS would meet the limitation of the stabilizing polymer taught by Babcock et al. Even assuming arguendo that the HPMCAS is not included in the scope of Babcocks et

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al. invention, Babcock et al. teach that HPMCAS and CAP can be added for stabilization.

Applicant further argues that claim 20 recites “consisting of HPMCAS and CMEC” and therefore excludes addition of other stabilizing polymers. Applicant’s argument has been fully considered. Claim 20 recites “the stabilizing polymer is selected from the group consisting of HPMCAS and CMEC”. This is a Markush style claim limitation and not a limitation on the contents of the composition. However the claim recites comprising language with regard to the elements of the composition (“said particles comprises”). Therefore, the claim may contain stabilizing polymers other than those in the Markush group. Therefore, even if one of ordinary skill in the art would not have been motivated to use HPMCAS alone, they would have been motivated to use both HPMCAS and CAP which would still read on the instant claims.

The rejection of claims 20-34 under 35 U.S.C. 103(a) as being unpatentable over Beyernick et al. (US Patent Application 2003/0163931 A1, Published 09/04/2003) in view of Infeld et al. (International Application Published Under the PCT WO 02/089835 A2, Published 11/14/2002) in view of Applicant’s argument is withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALI SOROUGH whose telephone number is (571)272-9925. The examiner can normally be reached on M-F (9am-6pm).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571)272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ALI SOROUGH/
Examiner, Art Unit 1617

October 11, 2011